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AND SRI LANKA

February 25, 2022

VIA ECF

The Honorable Thomas Vanaskie
Special Discovery Master
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19102

The Honorable Robert B. Kugler
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-KW

Dear Judges Kugler and Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on February 28, 2022. Defendants do not anticipate that discussion of the topics listed in the agenda will concern confidential and/or restricted confidential information.

1. Dismissal of CVS from the Medical Monitoring Master Complaint.

As other Pharmacy Defendants have done, CVS requests dismissal from the Medical Monitoring Master Complaint ("MMMC"), as no remaining putative class representative alleges that he or she filled valsartan from CVS and is pursuing a claim against it. Therefore, CVS requests

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Plaintiffs be ordered to show cause why CVS should not be dismissed from the MMMC. Counsel sent multiple emails to the Plaintiffs' Executive Committee requesting CVS be dismissed from the MMMC, but Plaintiffs' counsel has not responded. *See* Exhibit 1.

In addressing traceability, Judge Kugler explained that “in order to establish standing in the class action context, for each named defendant, at least one named plaintiff must be able to allege an injury traceable to that defendant.” MTD Op. 2 (ECF No. [728](#)) at 17. In response to the Pharmacy Defendants' traceability arguments on the Plaintiffs' Motion for Leave to Amend, Your Honor noted that “it appears that there remain untraced” certain pharmacy defendants where no named plaintiffs alleged they filled a valsartan prescription at those pharmacies. ECF No. [1614](#) at 7. Thus, Your Honor gave Plaintiffs the “opportunity to show cause why the claims asserted [against these untraced defendants] should not be dismissed with prejudice.” *Id.*; *see also* ECF No. [1615](#) ¶ 11. Plaintiffs did not respond to the order to show cause with respect to the Pharmacy Defendants identified in that round of briefing and did not name those defendants in their subsequently filed amended complaints. Specifically, Plaintiffs did not name Albertson's, Humana, Kroger, OptumRx in the MMMC (ECF No. [1709](#)), and did not name Humana in the ELMC (ECF No. [1708](#)). Pharmacy Defendants Rite Aid and Walgreens requested that they be dismissed from the MMMC on this same basis in the January 17, 2022 letter to this Court (ECF No. [1873](#)), and Plaintiffs agreed, filing dismissals on January 18, 2022 (ECF No. [1880](#)).

Subsequent to Your Honor's October 8, 2021 Opinion and Order and the January 18, 2022 dismissals of Rite Aid and Walgreens, Plaintiffs voluntarily dismissed the claims of Celestine Daring and Richard O'Neill. *See* ECF Nos. [1913-1914](#). Following these dismissals, there are no putative MMMC class representatives with a pending claim against CVS who allegedly filled a valsartan prescription from CVS.

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One Plaintiff, Sylvia Cotton, is identified in the MMMC as a representative of a medical monitoring sub-class for the State of Texas. However, Plaintiffs do not assert claims against CVS (or any pharmacy defendant) under Texas law in the MMMC. See, e.g., Ex. A to Plaintiffs' Medical Monitoring Class Certification Motion, ECF No. [1750-1](#). This non-assertion of a claim against the Pharmacy Defendants under Texas law is consistent with rulings made by the Court, including the Court's dismissal of independent medical monitoring claims under Texas law (as well as various other states) and dismissal of breach of implied warranty claims against the Pharmacy Defendants under Texas law (as well as various other states). See ECF No. [775](#) at 4; see also ECF No. [776](#) at 3; ECF No. [838](#) at 32-33; and ECF No. [839](#) at 5. Thus, Ms. Cotton does not have a pending claim against CVS or any other pharmacy defendant.

Another Plaintiff, Paulette Silberman, references CVS in the amended complaint (ECF No. 1709 at ¶ 27), but per Ms. Silberman's deposition testimony, CVS did not sell or dispense any valsartan products to Ms. Silberman. Ms. Silberman testified that she filled valsartan at a pharmacy within a QuickChek grocery store and never received valsartan from a CVS store. See Silberman Transcript, Exhibit 2, at 132:8-10 (Ms. Silberman confirming she never received any valsartan from a CVS store); see also *id.* at 49:8 ("[I]t was always QuickChek.").

Thus, there are no remaining class representatives with medical monitoring claims against CVS and thus no traceability for purposes of standing in the MMMC. CVS should be dismissed from the MMMC.

2. The Marker Group's Data Breach.

On February 2, 2022, Greenberg Traurig received a form letter providing notice of a security event affecting data stored by the Marker Group ("Marker"), which is the third-party

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vendor the parties use in this litigation to collect and host plaintiff-specific records. Marker's letter specifically stated that Marker would be providing notice directly to the individuals whose data was impacted, as well as to the appropriate regulatory authorities. According to Marker, the event impacted 88 plaintiffs in this litigation, as well as a number of plaintiffs in many other litigations. The Marker security event is the subject of at least one class action lawsuit filed in January of 2022 in the Southern District of Texas by Morgan & Morgan, a firm who also serves on the Plaintiff's Personal Injury PSC in this litigation.

Defendants are working to understand the scope and nature of Marker's event and obtain assurances about tightened security protocols, however, Marker is in the best position to provide the information Plaintiffs seek, to describe what happened, and to explain how they are addressing it. We have offered to facilitate a call between Marker and Plaintiffs' counsel, even though Plaintiffs also interface directly with Marker, as well as suggested that Plaintiffs' counsel reach out to Marker directly. We have also provided Marker's letter notice and Marker's list of valsartan plaintiffs whom they believe were impacted, and said we would make ourselves available for a call to discuss further. Thus, we do not believe there is any dispute that is ripe for the Court's adjudication, but we will be prepared to discuss further with the Court if needed.

3. Rule 702 *Daubert* Hearing Schedule.

Per the Court's instructions, the parties submitted supplemental declarations on February 24, 2022, in connection with pending Rule 702 motions concerning general-causation experts. The disclosures were made simultaneously such that, at the time of submission, neither Plaintiffs nor Defendants were aware of which experts, if any, the other side intended to present or the scope of any witness's supplemental disclosure. Defendants nonetheless noted, ECF No. [1929](#), at 2, their concern with respect to the procedure envisioned by the Court whereby the party proffering an

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expert gets to decide not only which witnesses are to be subjected to cross examination but also the topics upon which those witnesses may be examined. Defendants are concerned that the process—which does not presently contemplate the presentation of live direct testimony, oral argument, or the receipt of evidence beyond the supplemental declarations and limited cross examination—may not create an adequate record, given the significance of the issues raised and the magnitude of this litigation.

Upon receipt of Plaintiffs' disclosure, ECF No. [1928](#), Defendants continue to harbor those concerns. Plaintiffs have produced supplemental declarations from only three of their five experts, none of which directly bear on the central issue to be decided—i.e., whether Plaintiffs can prove, through expert testimony supported by sound scientific methodology, that reasonably anticipated levels of exposure to two particular impurities in valsartan-containing medications is capable of causing the thirteen cancers placed at issue, *see* ECF No. [706](#). Dr. Panigrahy, for example, offered a 250-page general-causation report containing over 500 citations, ECF No. [1716-3](#), but his supplemental certification is limited to six paragraphs discussing the bioavailability of NDMA through animal studies, ECF No. [1928-2](#). Based on prior statements from the Court, Defendants understand their cross examination of Plaintiffs' experts will be limited to the four corners of the supplemental declaration. If so, the Court will be deprived of the opportunity to hear live testimony from Plaintiffs' witnesses concerning the vast majority of their opinions and the supposed bases thereof.

Respectfully, therefore, Defendants request the Court to schedule full evidentiary hearings in order to resolve the pending Rule 702 motions. Defendants believe that the general-causation issue must be considered with the benefit of robust cross-examination on the totality of an expert's

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report, the presentation of live direct testimony, the taking of oral argument, and the receipt of other evidence bearing on the admissibility of the proffered experts' opinions.

Assuming the Court is inclined to proceed with the process it previously outlined, Defendants met and conferred with Plaintiffs' counsel on February 25, 2022, and offered potential dates for the *Daubert* hearings related to Defendants' two general causation experts who submitted declarations, Dr. George Johnson and Dr. Michael Bottorff, ECF No. [1929](#). Defendants offered March 15, 2022, for Dr. Bottorff, subject to clarification on Judge Vanaskie's emails as to which date the Court is available. Dr. Johnson is unavailable on March 2, 3, 14, or 15, but is available on March 29, 2022, assuming it can be accommodated by the Court's schedule. Defendants will update the Court on agreed dates for these experts once Plaintiffs respond. Plaintiffs indicated that all three of their witnesses would be called on March 2, 2022, and that hearings would continue as necessary on March 3, 2022. Plaintiffs declined to offer any information on the order of their witnesses. The parties will continue to work to finalize the schedule in advance of next Monday's conference.

4. Plaintiffs Fact Sheets/Show Cause Listings

Cases Addressed at the February 2, 2022 Case Management Conference:

The Court issued three show cause orders returnable at the February 28, 2022 Case Management Conference:

- *Shylaine Louissant v. Mylan, et al.* - 21-cv-07797
- *Charlene Mills v. Actavis, et al.* - 21-cv-13611
- *Jimmie Thorn v. Mylan, et al.*, - 20-cv-20603

The issues in the *Louissant* matter are resolved, and the show cause order may be withdrawn.

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The issues in the *Mills* and *Thorn* matters remain unresolved, but the parties are working towards a resolution and request a one-month extension of these two orders to show cause until the March 30, 2022 Case Management Conference.

Second Listing Cases – Order to Show Cause Requested:

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases were previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on February 16, 2022, and a global meet and confer was held on February 18, 2022. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the February 28, 2022 Case Management Conference:

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Robert Cook v. ZHP, et al.	1:21-cv-17184	Watts Guerra	<p>- IV.E.3 - Failed to provide complete information. Naquoia Cook is identified as Plaintiff's daughter but is not listed under children in Section II.B.3</p> <p>-VII.A.1.a - Plaintiff checked box "No" for ever having been diagnosed with cancer more than once but Plaintiff's claimed injury is Colon Cancer (I.D.3) and medical records and Death Certificate indicate Plaintiff was diagnosed with non-Hodgkin's lymphoma (see X.A.). Please clarify apparent inconsistency.</p>	11/26/2021

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2.	Martin Scott v. ZHP, et al.	1:21;-cv-17216	Watts Guerra	No insurance or worker's compensation and/or disability authorizations were provided	11/26/2021
3.	Tracy Whitfield v. ZHP, et al.	1:21-cv-15076	Oliver Law Group	Failed to respond to numerous deficiencies identified in Notice – only provided some acceptable authorizations	12/2/2021
4.	Curtis McCall v. Aurobindo Pharma	21-cv-13859	Serious Injury Law Group, P.C.	No PFS filed	PFS due – 11/06/2021
5.	Deborah Harris v. Aurobindo Pharma	20-cv-19164	Serious Injury Law Group, P.C.	No PFS filed	PFS due – 02/13/2021
6.	Ernestine Williams v. Mylan Pharmaceuticals., et al	1:21-cv-06946	Douglas and London	No PFS Filed.	PFS Due - 11/9/2021

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs leadership on February 16, 2022 and a global meet and confer was held on February 18, 2022. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	James Larsen v. Actavis, et al.	21-cv-18313	Newlands and Clark	Need medical expenses, missing date range for treatment from Dr. Thomas Ganey, missing dates of hypertension onset.	12/28/2021

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2.	Gerald Henning v. ZHP, et al	21-cv-17989	Levin Papantonio	Need medical expenses.	1/7/2022
3.	Estate of Carl Willix v. Aurobindo, et al	21-cv-17992	Levin Papantonio	Need medical expenses	1/24/2022
4.	Richard Verrier v. Aurobindo Pharma, Ltd.	21-cv-20370	Watts Guerra	Missing pharmacy documentation/NDC codes for entries 2-7. Need complete medical expense information; need United Healthcare dates of service; need several missing medication history sections filled in.	2/11/2022
5.	Estate of William Byrnes v. Aurobindo, et al	21-cv-13325	Stark & Stark	Need date range for product use; no cancer diagnosis information	2/5/2022
6.	Elnita Brooks v. Aurobindo Pharma, Ltd.	21-cv-18001	Levin Papantonio	Need medical expenses	2/15/2022
7.	Deborah Harris – Estate of Donald Harris v. Aurobindo Pharma, Ltd., et al	21 - CV-06395	Arnold & Itkin, LLP	No authorizations, Incomplete PFS, no NDC codes or identification that recalled product was consumed	01/25/2022
8.	Estate of Sloan Mitchell v. Aurobindo	21- CV-20355	Watts Guerra	No authorizations for Dr. Michael Gainey and Dixie Stone PA-C No Medical expenses	02/11/2022
9.	Robert Anderson v. Hetero Drugs, Ltd., et al.	21-cv-18338	Hollis Law Firm, PA	III.G.c – Failed to provide the monetary amount for identified claimed medical expense.	1/26/2022

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				<p>XI.B.2 – No Walgreens pharmacy records produced.</p> <p>XI.B.18 – No billing records produced.</p> <p>XII – No executed declaration produced with Amended PFS.</p>	
10.	Brian Nahmis v. Zhejiang Huahai Pharmaceutical Co., Ltd. et al	21-cv-18002	Levin Papantonio	Need medical billing and tax records; PFS needs to be amended to include answers from response to deficiency notice	1/4/2022
11.	Claudette Pelletier v. Aurobindo Pharma Ltd.	21-cv-17676	Morgan & Morgan	Failure to list all medications in VI.A.	1/20/2022
12.	Jeffrey S. Williams v. Aurobindo Pharma	21-cv-16345	Heninger Garrison Davis LLC	Authorizations improperly dated, failure to respond at all to deficiency notice, failure to list salary, medical expenses, healthcare providers	1/20/2022
13.	Kelly Donaldson v. Aurobindo Pharma	21-cv-18272	Newlands and Clark	Failure to provide dates of taking Valsartan; failure to list dates she was treated by doctors	12/29/2021
14.	The Estate of Denise Kadish v. Zhejiang Huahai Pharmaceutical Co., Ltd. Et al.	21-cv-16239	Levin Papantonio	PFS needs to be amended to include answers from response to deficiency notice	12/23/2021
15.	Norris Booth v. ZHP, et al.	21-cv-18336	Hollis Law Firm	Failed to provide signed Declaration for Amended PFS	1/10/2022

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16.	Matthew Blain v. ZHP, et al.	21-cv- 19442	Fleming, Nolez and Jez	Missing records/documents responsive to Section XI.B.20	1/18/2022
17.	Michael Ferguson v. ZHP, et al.	21-cv- 15425	Hollis Law Firm	Failed to provide signed declaration for Amended PFS	1/18/2022
18.	Anthony Mixon	21-cv- 19958	Levin Papantonio	No PFS Filed.	1/12/22
19.	Eric Thompson	21-cv- 19973	Levin Papantonio	No PFS Filed.	1/12/22
20.	John McDermott	21-cv- 20426	Levin Papantonio	No PFS Filed.	2/9/22
21.	Mary Powell	21-cv- 20436	Levin Papantonio	No PFS Filed.	2/9/22
22.	Eileen D'Imperio	21-cv- 20457	Levin Papantonio	No PFS Filed.	2/10/22
23.	Tom Maestas	21-cv- 20458	Levin Papantonio	No PFS Filed.	2/10/22
24.	Chadwick Wilson	21-cv- 20624	Morgan & Morgan	No PFS Filed.	2/21/22
25.	Anthony Scavone	21-cv- 20692	Morgan & Morgan	No PFS Filed.	2/23/22
26.	Thomas Donahue	21-cv- 16348	Stark & Stark	No PFS Filed.	10/31/21

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27.	Roderick Redmon	21-cv-14198	Stark & Stark	No PFS Filed.	10/24/21
28.	William Webb	21-cv-14427	Levin Papantonio	No PFS Filed.	9/30/21

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

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